K000318

FEB 28 2000

Summary of 510(k) Premarket Notification

(a)(1) Submitter's name, address and contact:

Bionostics, Inc.
2 Craig Road
Acton, MA 01720

Contact: Kathleen Storro
Director Quality Assurance and Regulatory Affairs
Telephone No.: 978-263-3856, ext. 220
E-mail: kstorro@bionosticsinc.com

Date Summary Prepared: January 20, 2000

(a)(2) Device trade name:

Bionostics Glucose Quality Control Solution
For use with the Fast*Take*® Compact Blood Glucose Monitoring System

Classification Name: Single Analyte Controls (Assayed and Unassayed)
Classification Number and Class: 75JJX, Class I

(a)(3) Substantial Equivalence

The Bionostics Glucose Quality Control Solution for use with the Fast*Take*® Compact Blood Glucose Monitoring System is substantially equivalent in function, safety and effectiveness to the Fast*Take*® Control Solution currently being marketed by LifeScan Inc., Milpitas, California 95035.

This 510(k) notification contains information showing substantial equivalence with the existing Fast*Take*® Control Solution.

(a)(4) Description of the New Device

The Bionostics Glucose Quality Control Solution is a non-hazardous aqueous glucose control solution. The control contains no biological based materials.

The Bionostics Glucose Quality Control Solution product is packaged in plastic bottles, which have dropper tips for application of the solution to test strips. The control has a red color to help users see drops of solution when dispensing the liquid onto a test strip.

(a)(5) Intended Use:

The Bionostics Glucose Quality Control Solution is for use with the Fast*Take*® Meter and Fast*Take*® Test Strips as an assayed quality control check to verify the accuracy of blood glucose test results.

This product is for In Vitro Diagnostic Use.

(a)(6) Technical Characteristics of the Device

The Bionostics product is an aqueous solution containing glucose, red dye and preservatives. The solution is adjusted to have a viscosity to simulate the reaction of whole human blood when used on the Fast*Take*® Compact Blood Glucose Monitoring System.

The product contains no biological based materials.

(b)(1)(2) Summary of performance testing submitted with the premarket notification for the device

The Bionostics Glucose Quality Control Solution and the Fast*Take*® Control Solution were tested on the Fast*Take*® Compact Blood Glucose Monitoring System using Fast*Take*® test strips. The tests were performed to evaluate the response and the precision over several different temperatures.

(b)(3) Conclusions drawn from the testing of the device:

The tests verify that the Bionostics Glucose Quality Control Solution provides test response and precision that compare favorably with the Fast*Take*® Control Solution. The Bionostics control is therefore substantially equivalent in performance to the Fast*Take*® Control Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 28 2000

Ms. Kathleen Storro
Director of Quality Assurance and Regulatory Affairs
Bionostics, Inc.
2 Craig Road
Acton, Massachusetts 01720

Re: K000318
Trade Name: Bionostics Glucose Quality Control Solution
For use with FasTake® Compact Blood Glucose Monitoring System
Regulatory Class: I
Product Code: JJX
Dated: January 20, 2000
Received: February 1, 2000

Dear Ms. Storro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K000318 (not yet assigned)

INDICATIONS FOR USE:

Device Name: Bionostics Glucose Quality Control Solution
For use with the Fast*Take*® Compact Blood Glucose Monitoring System

A. INDICATIONS FOR USE:

The Bionostics Glucose Quality Control Solution is for use as a quality control check to verify the performance of the Fast*Take*® Compact Blood Glucose Monitoring System. It is an assayed OTC product intended for use with the Fast*Take*® Compact Blood Glucose Monitoring System in the home setting.

This product is for In Vitro Diagnostic Use.

(Division Sign-Off)
Division of Clinical Laboratory
Number K000318

OTC ✓

Revised 02/24/00